

## Exhibit 84

# DEA aims big to stem painkiller black market

Donna Leinwand Leger . USA TODAY ; McLean, Va. [McLean, Va]28 Feb 2012: A.1.

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## ABSTRACT

The state Medical Examiner's Office recorded 4,048 deaths from hydrocodone, hydromorphone, oxycodone and oxymorphone in 2010, up 24% from 2009. [...] last year, doctors could dispense the painkillers from their offices.

## FULL TEXT

Vincent Moellering heard a rumor in April 2009 that a local pharmacy was selling the powerful and addictive painkiller oxycodone by the pill for cash. So Moellering, an investigator for Cardinal Health, one of the nation's largest distributors of pharmaceuticals, visited Gulf Coast Medical Pharmacy in Fort Myers, Fla.

Over the next two years, Moellering and other Cardinal employees visited that pharmacy at least four more times. Each time, they noted disturbing signs: Customers paid cash, oxycodone was the No. 1 seller, and young people came in groups to have their prescriptions filled.

On Oct. 5, 2010, Moellering's fourth visit, pharmacy owner Jeffrey Green told him he wanted more oxycodone. The store had dispensed 462,776 pills over two months -- nearly seven times what the average pharmacy dispenses in a year. Convinced something was off, Moellering asked Cardinal's permission to contact the Drug Enforcement Administration, according to documents filed in federal court.

The DEA says the call never came. Cardinal would not make Moellering available for comment and declined to explain why he never made the call. Cardinal granted Green's request for more oxycodone but stopped serving the pharmacy a year later.

This month, the DEA accused Cardinal Health, a Fortune 500 company with \$103 billion in revenue, of endangering the public by selling excessive amounts of oxycodone to four Florida pharmacies. The charges came in an immediate suspension order served Feb. 3 when the agency suspended Cardinal's license to distribute controlled substances from its Lakeland, Fla., hub, which serves four states.

Cardinal challenged the suspension in federal court. U.S. District Judge Reggie Walton temporarily halted the DEA's suspension and scheduled a hearing for Wednesday. In preparation for the hearing, the DEA and Cardinal have filed hundreds of pages of documents that provide an inside look into how prescription painkillers such as oxycodone and hydrocodone have flooded the black market.

The investigation into Cardinal led the DEA to suspend the licenses of four of the company's largest Florida customers, including Gulf Coast and two CVS pharmacies in Sanford, Fla. Like Cardinal, CVS challenged the suspensions in federal court.

The suspensions are an aggressive display of the DEA's strategy to attack the prescription drug abuse problem at the highest levels. After years of cracking down on doctors who dispense drugs from clinics known as pill mills, DEA agents are targeting the top of the supply chain as part of a comprehensive strategy to stop the flow of prescription drugs to street dealers.

More than 5 million people in the USA abuse narcotic painkillers. The Centers for Disease Control and Prevention classifies prescription drug abuse as an epidemic. More than 27,000 died from prescription drug overdoses in 2007, a fivefold increase since 1990, which parallels a tenfold increase in the medical use of painkillers such as oxycodone and hydrocodone, the CDC reports.

"The number of overdose deaths involving prescription pain medication is staggering and now exceeds deaths from heroin and cocaine combined," said Gil Kerlikowske, director of the White House Office of National Drug Control Policy. "Just because prescription painkillers aren't sold out of a piece of tinfoil by a drug dealer lurking in a back alley doesn't mean they're not dangerous."

Kerlikowske said the federal steps to control the epidemic are mindful of the need to protect access to the medications for legitimate patients.

Doctors prescribe oxycodone and hydrocodone to treat severe pain after surgery or during cancer treatment. Doctors also use the drugs to treat people with illnesses and injuries that cause chronic pain. Hydrocodone is nearly as potent as morphine for pain relief. The drugs -- synthetic versions of the compounds found in opium -- are highly addictive and can produce a heroin-like high. Drug abusers may crush the time-release tablets and inject or snort the medicine to get the most potent high. People who consume too much of the drug may have trouble breathing, slip into a coma or die.

Florida, which had lax laws governing pain clinics until last year, is at the focal point of prescription painkiller abuse. The state Medical Examiner's Office recorded 4,048 deaths from hydrocodone, hydromorphone, oxycodone and oxymorphone in 2010, up 24% from 2009. Until last year, doctors could dispense the painkillers from their offices. Now doctors must write prescriptions to be filled at pharmacies.

#### Watching the supply chain

Under the federal Controlled Substances Act, the DEA regulates every link in the supply chain for controlled substances such as oxycodone and hydrocodone, including manufacturers, distributors, doctors and pharmacies. About 1.4 million entities have DEA licenses, called registrations, to handle the controlled pharmaceuticals. Within the closed system, each license holder has responsibilities to maintain control of the drugs and keep them from getting to illegitimate players, DEA Special Agent Gary Boggs said.

The law requires distributors, such as Cardinal Health, to have systems to detect suspicious orders, which must then be reported to the DEA. The agency repeatedly warns distributors that the size of an order alone triggers the distributor's responsibility to report it to the DEA, Boggs said. Distributors must cut sales to those drugstores with suspicious orders even if they have a valid DEA license, he said.

"If all those players involved are either complicit or not doing their due diligence correctly, that whole system comes tumbling down," Boggs said.

In court documents filed in response to Cardinal's challenge, the DEA calls the company's sales to the four pharmacies "staggeringly high" and says Cardinal ignored red flags raised within its own system to detect suspicious orders.

"Our system did raise questions with these four pharmacies," said Cardinal spokeswoman Debbie Mitchell. "We took decisive action and voluntarily suspended shipments of controlled medicines to two late last year. As for the two national chain pharmacies, we raised questions with their corporate headquarters, which they addressed. CVS subsequently took action to stop filling prescriptions for 22 doctors."

Cardinal argues that volume alone is not enough to determine whether a pharmacy is diverting the drugs, because it does not account for a pharmacy's location, the age and health of the population, and the proximity to hospitals, nursing homes and cancer centers.

"If the problem were that simple, DEA could solve it simply by setting volume limits" on the pharmacies, Cardinal says in a document posted on its website.

Cardinal notes in court papers that it has a robust detection system and has cut off more than 330 pharmacies, including 140 in Florida, over the past four years that it determined posed an unreasonable risk of diversion. Although the company reported the pharmacies to the DEA, most still hold DEA licenses and continue to operate, the company said.

Distributors can act more quickly than law enforcement if they know something is wrong, Boggs said.

"We have to investigate things in a different manner than a company (that) can act on a suspicious order. We have to meet constitutional and legal requirements. They don't have to sell to someone," Boggs said. "They have a moral

obligation as keepers of powerful and dangerous substances to make sure those substances are used for legitimate medical purposes."

Looking for 'blatant signs'

According to court papers filed by the DEA and Cardinal, the four pharmacies sold thousands more pills than the average drugstore and had a high proportion of customers paying in cash. An average pharmacy in the USA dispenses 69,000 oxycodone pills a year of varying doses, the DEA said. Fewer than 7% of the patients nationwide pay for their prescriptions with cash.

"You can have the ostrich approach. You can stick your head in the sand and ignore blatant signs," Boggs said.

"This company is sitting in a state that has been the epicenter of the problem. It's no secret that the drug of choice is oxycodone. I don't think you have to be that strong of an investigator to put two and two together."

The DEA says Cardinal's Lakeland distribution center shipped 50 times as much oxycodone to its top four customers than it has shipped to its other Florida retail customers. Specifically:

CVS #219. In 2010, Cardinal shipped 2.05 million pills to the 24-hour store in Sanford, a town of 53,000 people north of Orlando, the DEA said. The numbers dropped in 2011 after CVS cut off the 22 doctors whom it suspected were writing illegitimate prescriptions. Still, Cardinal sold the pharmacy more than 1.8 million pills – an average of 137,994 pills a month. Cardinal's other customers in Florida averaged 5,364 oxycodone pills a month.

About 42% of the CVS store's customers paid cash, the DEA said in court papers.

CVS #219 pharmacist Paras Priyadarshi told DEA investigators that the pharmacy's fastest-moving controlled substance was 30-milligram oxycodone, DEA group supervisor Ruth Carter said in a sworn statement filed as part of the federal court proceedings. Doctors often used the same diagnosis code on multiple prescriptions and often prescribed to two people living at the same address, which Carter said are signs of diversion.

Carter, in the sworn statement, said Priyadarshi told her customers often requested certain brands of oxycodone using street slang.

In a sworn statement in CVS' challenge to the DEA, Priyadarshi said the DEA misinterpreted his statements.

Pharmacist Susan Masso, who has worked at CVS #219 since June, said she would not fill prescriptions she thought were illegitimate. "I will not fill any prescription for any highly addictive drug, such as oxycodone, for any person who appears intoxicated or otherwise impaired," she wrote in a sworn statement filed in the CVS case.

Masso learned of the DEA concerns after agents interviewed her twice in October. She said the store took steps to reduce the risk of abuse and diversion. Besides suspending the 22 practitioners "who represented the majority of the oxycodone prescriptions," the pharmacy reduced the geographic area for doctors it served. As a result, the pharmacy has "dramatically reduced its ordering and dispensing of oxycodone," she said.

DEA investigators serving a warrant Oct. 18 noted that "approximately every third car that came through the drive-thru lane had prescriptions for oxycodone or hydrocodone," Carter said. "Priyadarshi knew that his store filled more oxycodone prescriptions than any other CVS in his district, but he reported that no one from CVS corporate had said anything to him about the high volume at the store."

CVS #5195. A few miles away in Sanford, this CVS store dispensed more than 58,000 oxycodone pills a month, and 58% of the customers paid cash, the DEA said. From 2009 to 2010, the number of oxycodone pills the pharmacy purchased from Cardinal jumped to 885,900 from 104,500. In 2011, the CVS purchased more than 1.2 million pills. Although Cardinal's electronic system for monitoring suspicious orders flagged the CVS orders 22 times for further investigation, Cardinal never held a shipment, notified the DEA or sent an investigator to visit the store, the DEA said.

CVS pharmacist Jessica Merrill described the oxycodone customers as "shady," Carter said.

"Cardinal shipped enough oxycodone for every man, woman and child in Sanford to have 59" pills in 2011, the DEA said.

In a sworn statement filed in the CVS case, Merrill said the DEA's account of her interview with Carter is inaccurate. She said Carter used the term "shady," and when she asked what the agent meant, Carter said people filling oxycodone prescriptions except cancer patients are drug seekers.

Merrill said she instructs pharmacists and technicians to reject prescriptions from people who have pinpoint pupils, show aggression or don't have a consistent medical history. The store keeps a binder on suspected doctor shoppers, which it shares with local law enforcement, she said. "I have assisted in at least 15 arrests related to oxycodone" since the end of 2009, Merrill said.

"I have never filled a controlled substance prescription, nor directed anyone else to do so, based on a belief that filling such a prescription would affect any bonus I received from CVS," Merrill said.

She estimates the store rejected about 10% of the prescriptions it received each day.

Michael Mon, Cardinal's vice president for anti-diversion, said in court papers that Cardinal's shipments to the pharmacies in Sanford "did not appear unreasonable."

"It is reasonable and not uncommon" for doctors to prescribe a 30-day supply of four to six, 30-milligram oxycodone pills a day for a person in chronic pain, Mon said. The amount of oxycodone Cardinal delivered to six pharmacies in Sanford would fill 26,201 four-pill-a-day prescriptions, he said.

CVS, in a statement issued Feb. 17 in response to questions from USA TODAY, said the company is committed to working with the DEA and had taken "significant actions to ensure appropriate dispensing of painkillers in Florida, which have already resulted in dramatically reduced distribution of oxycodone."

For instance, spokesman Mike DeAngelis said, the number of oxycodone pills dispensed by the two Florida pharmacies dropped 80% in three months after CVS stopped filling some narcotics prescriptions for the 22 doctors writing questionable prescriptions. The company developed specific guidelines to help pharmacists determine whether prescriptions are legitimate, he said.

Brooks Pharmacy. The Bonita Springs pharmacy, also called Caremed, was Cardinal's fourth-largest customer in Florida. Cardinal's sales of oxycodone to Brooks more than tripled from 231,740 doses in 2009 to 724,500 doses in 2010, the DEA said. Owner Roscoe Heim asked for another increase in March 2010, claiming the chain drug stores in the area had stopped carrying controlled substances because they didn't want to deal with DEA paperwork, according to a letter he wrote to Cardinal that was filed with the court. "Many physicians are requiring patients to sign contracts using one pharmacy only for controlled substances, and they are referring their patients to us because we specialize in pain management," Heim wrote to Steve Morse at Cardinal Health.

Moellering concluded on his third visit to the store Sept. 21, 2011, that the pharmacy was probably diverting drugs, according to his inspection report, which is included in court papers. Cardinal halted its sales that day. Brooks surrendered its DEA license voluntarily a month later.

Gulf Coast Medical. The pharmacy, located inside a medical office building in a complex next to a 480-bed hospital, was Cardinal's second-largest customer in Florida. It had a small, but well-stocked, over-the-counter medicine section and appeared to serve customers from the surrounding middle-class area, Moellering noted.

In 2011, as Moellering's concerns mounted, Cardinal sold more than 2 million oxycodone pills to Gulf Coast, an 868% increase since 2009. Police were closing in. In each of Cardinal's reports on Gulf Coast, Moellering listed the top prescribers whose patients used the pharmacy.

By the time Cardinal cut Gulf Coast off in October, police had arrested at least three doctors included in Moellering's reports and charged them with a variety of charges, including trafficking in oxycodone, racketeering and overprescribing narcotics.

On Jan. 19, a federal grand jury indicted Green, the pharmacy owner, for conspiracy to possess with intent to distribute oxycodone. Green has pleaded not guilty in federal court. His lawyer did not return a call for comment.

Credit: Donna Leinwand Leger, USA TODAY

### Illustration

GRAPHIC, Color, Julie Snider, USA TODAY (Line graph); Caption:

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